Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 27, 2010 May 7, 2012

LIORESAL® (intrathecal) /GABLOFEN® (baclofen)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

1. Continuation of intrathecal baclofen therapy:
    a. Medication must be requested by a neurologist. (Prescription must be signed by neurologist.)

2. Initiation of therapy:
    a. Age > 4 years

    b. Must have severe spasticity of spinal or cerebral origin (**multiple sclerosis, cerebral palsy, spinal cord injury, or traumatic brain)** which has proven unresponsive or ineffective to maximal dosing of oral baclofen OR documentation of unacceptable side effects from or intolerance to oral baclofen at an effective dose.

    c. Must have a positive response to a screening trial (for details on a screening trial refer below to DOSAGE and ADMINISTRATION). A positive response is defined as a significant decrease in muscle tone and/or frequency of and/or severity of spasms as indicated in official medical documentation

    d. Medication must be requested by a neurologist. (Prescription must be signed by neurologist.)

DOSAGE AND ADMINISTRATION:

Intrathecal dosage (Screening dose):

Adults: Recommended initial screening dose is 50 mcg intrathecally by barbotage over a period of at least 1 minute. The patient is observed over 4—8 hours. A positive response consists of significant decrease in muscle tone and/or frequency and/or severity of spasms. If the initial response is less than desired, a second bolus of 75 mcg intrathecally may be given 24 hours after the first dose, and observe for 4—8 hours. If the response is still inadequate, a final bolus of 100 mcg intrathecally may be given 24 hours later. Patients who do not respond to the 100 mcg dose should not be considered candidates for an implanted pump for chronic infusion.

Lioresal®(intrathecal) (baclofen)

DOSAGE AND ADMINISTRATION (cont.):

Children >= 4 years: The initial screening dose and procedure is the same as in adults, 50 mcg intrathecally initially (see Adult dosage). However, for very small patients, a screening dose of 25 mcg intrathecally may be tried first.

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Intrathecal dosage (Dose titration):
Adults: The screening dose that gave a positive response should be doubled and administered as a continuous intrathecal infusion over a 24-hour period, unless the efficacy of the screening bolus dose was maintained for >= 8 hours. In this case, the starting daily dose should be the screening dose delivered intrathecally over a 24-hour period. No dose increases should be given in the first 24 hours. After the first 24 hours, the daily dosage should be increased slowly by 10-30% increments for spasticity of spinal cord origin or 5-15% increments for spasticity of cerebral origin per 24-hour period, until a desired clinical effect is achieved.

Children >= 4 years: The screening dose that gave a positive response should be doubled and administered as a continuous intrathecal infusion over a 24-hour period, unless the efficacy of the screening bolus dose was maintained for >= 8 hours. In this case, the starting daily dose should be the screening dose delivered intrathecally over a 24-hour period. No dose increases should be given in the first 24 hours. After the first 24 hours, the daily dosage should be increased slowly 5-15% increments per 24-hour period, until a desired clinical effect is achieved.

Intrathecal maintenance dosage (Spasticity of spinal origin):
Adults: Maintenance dosage for long term continuous intrathecal infusion has ranged from 12 mcg/day to 2003 mcg/day, with most patients maintained on dosages of 300-800 mcg/day. There is limited experience with doses > 1000 mcg/day. Doses are titrated to response with the lowest possible effective dose utilized. During periodic pump refills, the daily dose may be increased by 10-40%, but no more than 40%, to maintain adequate symptom control. The daily dose may be decreased by 10-20% if patients experience side effects. A sudden large requirement for dose escalation suggests a catheter complication (i.e., catheter kink or dislodgement).

Lioresal® (intrathecal) (baclofen)

DOSAGE AND ADMINISTRATION (cont.):
Children >= 4 years: For children < 12 years, the average dose was 274 mcg/day intrathecally (24—1199 mcg/day). Dosage requirements for children > 12 years are not significantly different from adults. During periodic pump refills, the daily dose may be increased by 5-20%, but no more than 20%, to maintain adequate symptom control. The daily dose may be decreased by 10-20% if patients experience side effects. A sudden large requirement for dose escalation suggests a catheter complication (i.e., catheter kink or dislodgement).

Intrathecal maintenance dosage (Spasticity of cerebral origin):
Adults: Maintenance dosage for long term continuous intrathecal infusion has ranged from 22 mcg/day to 1400 mcg/day, with most patients maintained on dosages of 90-703 mcg/day. There is limited experience with doses > 1000 mcg/day. During periodic pump refills, the daily dose may be increased by 5-20%, but no more than 20%, to maintain adequate symptom control. The daily dose may be decreased by 10-20% if patients experience side effects. A sudden large requirement for dose escalation suggests a catheter complication (i.e., catheter kink or dislodgement).

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